04-624

1999

AMENDMENT AND EXTENSION OF THE RESEARCH COLLABORATION

BETWEEN

THE MINISTRY OF PUBLIC HEALTH OF THAILAND

AND

THE CENTERS FOR DISEASE CONTROL AND PREVENTION

UNITED STATES PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

1. INVOLVED PARTIES

The Parties to this collaboration, initiated in 1990 for an initial four-year period and extended for a further five-year period through August 7, 1999 and which agree hereby to extend the collaboration for a further five-year period extending through August 8, 2004, are the Centers for Disease Control and Prevention, Atlanta, United States Public Health Service, U.S. Department of Health and Human Services (hereinafter referred to as CDC) and the Ministry of Public Health of the Royal Thai Government (hereinafter referred to as the MOPH). The CDC and MOPH may be referred to hereinafter collectively as "the Parties".

2. NAME

The name of the activity described herein is the "**HIV/AIDS COLLABORATION (HAC).**" In the Thai language, the name for this activity is:

ศูนย์ความร่วมมือการวิจัยโรคเอดส์

Terminology used in this document is listed in Annex I.

3. PURPOSE AND DESCRIPTION

3.1 Goals

This collaboration is undertaken for the purposes of conducting joint epidemiologic, laboratory, operational, behavioral, and health education/media communication research and training related to HIV infection and AIDS in Thailand. The goal is to improve understanding of the occurrence of HIV infection and AIDS and the dynamics of its spread in Thailand, to provide a scientific basis for the planning, monitoring, and evaluation of intervention programs to prevent and control the disease in line with the prevention strategies outlined in the National AIDS Prevention and Control Policy of the Ministry of Public Health and to develop a sustainable structure in Thailand that can continue the activities and develop capacity for conducting HIV/AIDS research in the host country.

3.2 Benefits

This collaboration is intended for the mutual benefit of both Parties. The collaboration will focus on Thailand's high priority areas and urgent public health needs to study and control the epidemics of HIV infection and AIDS. The United States expects to benefit from the knowledge gained from epidemiologic and laboratory studies and by the evaluation of prevention strategies.

3.3 Location

The collaboration shall be based within the city of Bangkok, Thailand and its suburbs. It may involve activities and/or study sites at other locations within Thailand.

3.4 Qualifications

CDC is not a donor agency. The collaboration will not involve donations of financial or other aid to Thai governmental or non-governmental agencies or organizations.

4. STRATEGY

In order to meet the goals of capacity building and sustainability, the following strategies will be implemented by the Parties:

4.1 Development of Researchers

The collaboration will involve working with collaborating institutions to select potential candidate(s) to receive further training and/or work with the collaboration.

4.2 Institutionalize a Research Unit in MOPH

A Working Group appointed by the Executive Committee (as defined in section 6.3 of this collaboration) will continue discussions and propose appropriate strategy and actions for consideration by the Executive Committee. The agenda for discussion will include location of the research unit, budget, and staffing.

4.3 Expansion of Training Capacity

In order to facilitate the transfer of technology necessary to conduct research, the collaboration will provide on-site, national and international training opportunities to develop Royal Thai Government staff and institutional expertise in epidemiology, laboratory support and data management.

5. POLICY

5.1 Development of Overall Policy

The collaboration shall periodically present the progress of activities to the Executive Committee (as defined in section 6.2 of this collaboration) for its review. The Committee will set overall policy and suggest revisions of proposed research studies as required.

5.2 Approval of Formal Research and Studies

Individual formal research studies planned by the collaboration shall be proposed to collaborating institutions for advance approval before implementation. Any protocol involving human subjects or laboratory animals shall be referred to the Thai National Committee for Ethical Review of Human Subjects Research and the CDC Institutional Review Board (see Section 6.4) for review regarding ethical considerations of the appropriateness of the use of human or animal subjects in the proposed research. Protocols related to AIDS vaccine research must also be submitted to the Technical Subcommittee on AIDS Vaccine of the Thai National AIDS Committee as outlined in the National Guidelines for AIDS Vaccine Research. Upon the initiation of this collaboration, the Parties shall develop specific mechanisms, procedures, and timetables for the preparation, submission, review, and the approval or disapproval of study protocols for research to be undertaken by the collaboration.

5.3 Informal Consultations

The collaboration is authorized on an *ad hoc* basis to informally consult with and provide assistance -- upon advance approval by the Executive Committee (as defined in Section 6.2 of this collaboration) or the Senior Thai Investigator (as defined in Section 6.5 of this collaboration) or other designated liaison or

representative(s) -- with other institutions, organizations, or individuals.

5.4 Dissemination or Publication of Data or Results

5.4.1 No publication or dissemination of data resulting from this collaboration shall be made by the Parties or by any of its collaborating institutions without the joint mutual advance approval by the Executive Committee (as defined in Section 6.2 of this collaboration), or by its designated representative(s) or liaison, and by CDC, unless otherwise required by the laws of the participating countries.

5.4.2 Manuscripts about collaborative studies submitted for publication by any of its investigators or by participating investigators from collaborating institutions shall have the approval of all the principal investigators (or their designees) listed on the study protocol.

5.4.3 Authorship of publications based on collaboration studies should include investigators making substantial contributions of time and effort to the planning, implementation, data analysis, and writing of the specific manuscript in question. The order of authors in manuscripts should reflect the relative contributions of the various individual researchers involved. The selection and order of authorship for specific publications should be based on advance discussion and mutual agreement among the principal investigators.

5.5 Intellectual Property

In the event that intellectual property other than for publications described in Section 5.4 is created in the course of cooperation under this collaboration, Annex II to this Agreement will apply.

5.6 Preservation of Data and Specimens

Data and laboratory specimens collected by the collaboration shall remain under its control and custody or as may otherwise be specified in individual study protocols. Upon termination of the collaboration, transfer of custody shall be based on the principle of copying (or splitting) and sharing of such data

and/or specimens between the principal Parties and collaborating institutions.

5.7 National AIDS Prevention and Control Policy

This collaboration is intended to be fully consistent and complementary to the policies, principles, and priorities established in the National AIDS Prevention and Control Policy.

5.8 WHO and UNAIDS Participation

Upon the initiation of this collaboration, the Parties will invite the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) to support it, and agree that recognition appropriate to any such support which may be forthcoming would be desirable.

6. ORGANIZATION AND ADMINISTRATION

6.1 Advisory Council

An **Advisory Council** to the collaboration shall consist of a small number of senior MOPH and CDC officials (2 - 3 each). Members of the Advisory Council shall be apprised periodically of the activities of the collaboration for purposes of general guidance and review, and such members or their designees shall serve as contact persons with the collaboration.

6.2 Executive Committee

The MOPH will provide an **Executive Committee** for the collaboration, consisting of a small number (approximately 10) of senior public health officials and may include recognized HIV and AIDS experts from other key medical and health institutions. The Executive Committee shall meet twice a year and review collaboration activities in its role to provide broad direction, policy guidance, and recommendations of priorities and targets; it will also explore developmental potential for capacity building in research and related interventions.

6.3 Working Group of the Executive Committee

The Chairman of the Executive Committee may convene a Working Group on an *ad hoc* basis to develop plans of action or to address specific issues as necessary. The Working Group will normally be

composed of members of the Executive Committee, but persons not on the Committee may be appointed when deemed appropriate or necessary to accomplish the task.

6.4 Ethical Review Board

The existing **National Committee for Ethical Review of Human Subjects Research** of the Royal Thai Government shall be utilized as the Ethical Review Board of the collaboration to consider the ethical implications of proposed research involving human subjects. The National Committee for Ethical Review of Human Subject Research shall have the responsibility to review research protocols planned by the collaboration and to determine whether the proposed studies are ethical and humane. Revisions will be made as required by the authors of the proposed protocols in cooperation with the HIV/AIDS Collaboration.

All protocols must also be reviewed and approved by the CDC Institutional Review Board (IRB) responsible for research supported by the U.S. Public Health Service.

6.5 Thai Senior Investigator

The **Thai Senior Investigator** for the collaboration will be a senior MOPH official with primary responsibility for the collaboration on the Thai side. The Thai Senior Investigator shall serve as a liaison between the collaboration and the Advisory Council, the Executive Committee, and the MOPH. CDC shall be notified in writing of changes in the person designated by the MOPH as the Thai Senior Investigator.

6.6 U.S. Senior Investigator

The **U.S. Senior Investigator** for the collaboration will be the Chief of the International Activities Branch, Division of HIV/AIDS Prevention - Surveillance and Epidemiology, National Center for HIV, STD and TB Prevention, CDC. The U.S. Senior Investigator will have primary responsibility for the collaboration on the U.S. Government side. The MOPH shall be notified in writing of a change in the person designated as Chief of the International Activities Branch, serving as the U.S. Senior Investigator.

6.7 Collaboration Director

The **Director** of the collaboration will be a U.S. Government

employee of CDC approved by the MOPH. This individual should be a physician with scientific, epidemiological skills and experience.

6.7.1 The Director will be responsible for overall coordination and supervision of all activities and all staff of the collaboration in scientific, technical and administrative areas.

6.7.2 The Director shall serve as the primary liaison with CDC and other U.S. Government agencies, the World Health Organization, UNAIDS, and any other interested agencies or organizations.

6.7.3 On administrative, technical, policy and personnel matters related to employment by the U.S. Government, the Director will be supervised by the U.S. Senior Investigator.

6.7.4 On issues of Thai policy and clearance for activities, the Director will be guided by the Thai Senior Investigator.

6.7.5 Other U.S. Government employees that are assigned to the collaboration shall report to and be supervised by the Director. As with the Director, such other U.S. staff shall be nominated to and require advance approval by the MOPH.

6.8 Adjunct Director

6.8.1 Selection and Responsibilities

The Adjunct Director will be a Thai national selected by mutual consent and agreement of the Thai Senior Investigator, the U.S. Senior Investigator, and the Director. This individual should be a physician with scientific epidemiologic skills and experience. The Adjunct Director will work with and assist the Director in the development and implementation of collaboration activities.

6.8.2 Assignment from RTG Employment

If the proposed Adjunct Director is a current RTG employee, his or her appointment to this position shall be by assignment from his or her current agency to a full-time detail with the

collaboration, with simultaneous release from all other job and work-related responsibilities of his or her former position. The Adjunct Director shall continue to receive his or her RTG salary, benefits, and promotions as if he or she was still working for his or her supporting agency. Detail to the collaboration should not be on a "study leave" status, nor other basis which requires payback obligations or penalties.

6.9 RTG Staff

6.9.1 Selection and Responsibilities

RTG employees to be assigned to the collaboration as RTG staff shall be selected in consultation between the Director and the Thai Senior Investigator, in cooperation with other involved officials of the RTG. RTG staff shall be supervised by the Director and Adjunct Director. With cooperation and consent from the appropriate authorities, RTG Staff may be assigned from the MOPH, the University system, and/or other research institutions and agencies of the RTG.

6.9.2 Terms of Assignment

RTG staff shall be assigned on a full-time or part-time detail on loan to the collaboration in accordance with the procedures of the RTG and the institution or agency with which they are affiliated. RTG staff shall be released from all other job and work-related responsibilities of their former positions for the time period specified in the terms of reference. RTG staff shall continue to receive their RTG salary, benefits, and promotions as if they were still working for their supporting agency. Detail or loan to the collaboration should not be on a "study leave" status, or other basis which requires payback obligations or penalties.

6.10 Local Hire Staff

Local hire staff will be employed for and on behalf of CDC by the U.S. Embassy in Thailand under the rules and procedures followed by the U.S. Embassy. Local hire staff may include, but are not limited to, the following job categories: secretaries, drivers, clerks, cleaners, translators, watchmen, computer operators, administrators, assistants, bookkeepers, physicians, nurses, epidemiologists, laboratory technicians and scientists.

6.11 Affiliated Staff and Voluntary Staff

Affiliated staff may be employees of collaborating agencies and institutions working with and assisting the collaboration on specific studies or research activities on a part-time or ad hoc basis. **Voluntary staff** may be individuals willing to work without pay or other compensation for the collaboration. Any affiliated staff or voluntary staff proposed to work in offices or laboratories of the collaboration or to use its equipment or facilities must be approved specifically in advance by the Director, the HIV/AIDS Collaboration, to whom they will report.

6.12 Incidental Reimbursement and Compensation

CDC may provide, within its discretion, reimbursement for travel costs and incidental or miscellaneous expenses incurred on collaboration activities, or for assigned or invited travel or attendance at meetings related to collaboration activities, to RTG staff, local hire staff, affiliated staff, voluntary staff, and/or members of the Advisory Council, Executive Committee, or Ethical Review Board.

CDC may provide, within its discretion, compensation to RTG staff on full-time or part-time detail to the collaboration for "overtime" work in excess of the normal number of working hours for employees in Thailand, and/or for being on-call for 24-hour availability to work on activities which may require them.

7. SCOPE OF POTENTIAL ACTIVITIES

7.1 Priorities

Population groups at risk and, therefore of high priority, for collaboration studies are:

+ Intravenous drug users.
+ Female commercial sex workers
+ Women of reproductive age
+ Youths

Another high priority is to monitor the spread of the HIV epidemic in the general population and sentinel sub-populations thereof by the adaptation to Thailand of methodology for the implementation of national seroprevalence surveys. Priorities for collaboration activity may change upon the mutual consent of the Executive Committee and of CDC.